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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,100	09/20/2001	Francis J Carr	MERCK 2309	4360

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 11/10/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,100

Applicant(s)

CARR, FRANCIS J

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 16-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-15 in Paper No. 9 are acknowledged. The traversal is on the ground(s) that Group I-IV relates to a method of protein identification or screening via binding to a target. It is further argued that a search of the methods of Groups I-IV would not be co-extensive and would not represent a serious burden to the Office. This is not found persuasive because the methods of Groups I-IV are distinct with respect to the steps and elements or compounds employed in each of the methods, albeit, perhaps the same desired binding effect would be achieved. Accordingly, a prior art search requires that each of the different elements present in the methods of Groups I-IV be searched. This will impose undue burden of examination especially since not only US Patents are searched but non-patent literature searches as well. These searches are not co-extensive. A search of the non-patent literature requires a search of the different databases. Thus, each of the different methods requires different prior art searches and patentability determination.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Status of Claims

Claims 1-51 are pending in the application.

Claims 16-51 are withdrawn from consideration, as stated above.

Claims 1-15 are under examination.

Specification

The abstract of the disclosure is objected to because it uses abstract of the PCT application. Correction is required. See MPEP § 608.01(b).

The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.

The disclosure is objected to because of the following informalities: There are no Seq. ID Nos. for the peptide sequences at page 3, lines 8 and 9; page 5, lines 1 and 5; page 26, line 7.

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Applicants should check for other peptide or nucleic acid sequences without any Seq. ID. No. in the specification since they are too numerous to mention specifically.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors typographical e.g., "and or" at page 1, line 6; grammatical and/or idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The specification does not disclose a specific utility for the recited library. The instant application, page 2, lines 25-40 relates to a method of making a library but does not recite the biological role or significance of this library.

The court in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its

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broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an invention must have either an immediately apparent or fully disclosed "real world" utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . .[i]t is not a reward for the search, but compensation for its successful conclusion.

The claimed library of undefined structure is nothing more than a collection of undefined compounds which utility has not been specifically set forth. Until some actual and specific significance can be attributed to the library, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed library. Thus, there was no immediately apparent or "real world" utility as of the filing date.

Claim 15 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

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Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is indefinite as the body of the claim lacks the essential steps of identifying, screening and/or sequencing as recited in the preamble. The body of the claim does not recite any process steps, except for the providing of the library. "Providing" is not a positive, manipulate process step. It is not clear within the claimed context, the scope of what is included by the step i.e. how the library is provided. The combined or separate determination of identification, screening and/or sequencing steps are unclear as the single or combined steps of the three processes. It is not clear as to the maximum limit of the **more** than one protein. "Barcodes" are not defined in the specification, as used in the context of the claim. When applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the

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written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999).

B. In claims 2-4 and 8, the recited "nucleic acid encoding the proteins" lack antecedent support from the base claim. [This claim appears to be drawn to a different compound, nucleic acid]. Regarding claims 4 and 11, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

C. Claim 8 is unclear as to the used of the "barcode" sequence to design synthetic oligonucleotides, especially in the absence of positive support or description in the specification.

D. In claims 5, 8 and 11, "eg" (sic, e.g.) renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

E. In claim 12, it is not clear as to how the heavy and light chain is derived. Furthermore, the used of parenthetical statements in the claim is improper as every feature or compound

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recited in a claim becomes a part of the overall subject matter. By placing terms in parenthesis renders the claim ambiguous as to whether or not said statement should be disregarded.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 5-6, 9-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Hutchens et al (WO 98/59360). (This rejection is based on the interpretation that the claimed "barcode" can be any of motif or a marker or detectable moiety).

Hutchens discloses a method of identifying protein by screening e.g., proteins or diagnostic markers which comprises providing library of proteins which bind to a target wherein each individual protein includes a marker or detectable moiety ("barcode" sequence") that identifies the protein in each library. The proteins in the library is detected or identified by mass spectrometry. See e.g., page 11, lines 22 up to page 13, line 7; page 22, line 11 up to page 23, line 22. Accordingly, the process of Hutchens which recite specific components of the

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process steps fully meets the claimed invention, as broadly as it can be interpreted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hutchens in view of Markland et al (WO 92/15679).

Hutchens is discussed above. Hutchens does not disclose the use of protease, Factor Xa that acts on the recognition sites for endoprotease digestion. However, Markland discloses at page 21, lines 5-20 that display peptides having high affinity for the target may be quite difficult to elute from the target, particularly a multivalent target. One can introduce a cleavage site for a specific protease, such as Factor Xa, into the fusion protein so that the binding domain can be cleaved from the

genetic package. Such cleavage has the advantage that all resulting phage have identical coat proteins and therefore are equally infective. The step allows recovery of valuable gene which might otherwise be lost.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use protease digestion in the phage fusion method of Hutchens, specifically Factor Xa for the advantage provided by Markland above. Such advantage would motivate one having skill in the art since this advantage provides for the recovery of valuable genes which might otherwise be lost if protease cleavage is not used.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Mirkin et al discloses bio-barcodes based on oligonucleotide-modified nanoparticles.

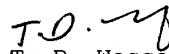
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
November 3, 2003